federal register

40 CFR Part 799

[OPTS-42067; TSH-FRL 2845-2]

Bisphenol A; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that manufacturers and processors of bisphenol A (4,4'-isopropylidenediphenol, BPA, CAS No. 80-05-7) be required, under the Toxic Substances Control Act (TSCA), to perform testing for 90-day inhalation subchronic toxicity with emphasis on pulmonary effects, and acute and chronic aquatic toxicity testing. This proposed rule is in response to the Interagency Testing Committee's (ITC's) designation of BPA for priority consideration for health and environmental effects testing.

DATES: Submit written comments on or before July 16, 1985. Make requests to submit oral comments by July 1, 1985. If requests are made to submit oral comments, EPA will hold a public meeting on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VI of this preamble.

ADDRESS: Submit written comments in triplicate identified by the document control number (OPTS-42067) to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm E-108, 401 M St., SW., Washington, D.C. 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday though Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Rm. E-543, 401 M St., SW., Washington, D.C. 20460. Toll free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of BPA for health and environmental effects testing consideration.

I. Background

A. ITC Recommendation

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2010 *et seq.*; 15 U.S.C. 2603 *et seq.*) established the ITC to recommend

to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated BPA (CAS No. 80-05-7) for priority consideration in its 14th Report submitted to EPA on May 8, 1984. The report was published in the **Federal Register** of May 29, 1984 (49 FR 22389). The ITC recommended that BPA be considered for chemical fate testing, including octanol/water partition coefficient and persistence, health effects testing, including reproductive effects, chronic effects and oncogenicity specifically as a result of inhalation exposures, and ecological effects testing, including acute and chronic toxicity to fish, aquatic invertebrates, and algae, and bioconcentration. The bases for these recommendations were as follows: annual production of 479 million pounds, estimated occupational exposure of 9,446 workers, expected environmental releases from manufacture and processing, and lack of sufficient data to characterize the effects of concern for BPA.

B. Test Rule Development Under TSCA

Under section 4(a) of TSCA, the EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test data if the Administrator finds that:

> (A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
> (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
> (B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
> (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight of evidence approach in making section 4(a)(1)(A)(i) findings; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure and release. For the findings under sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine if existing information is adequate to reasonably determine or predict the effects of human exposure to or environmental release of the chemical. In making the finding under section 4(a)(1)(A)(iii) or 4(a)(1)(B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules. The section 4(a)(1)(A) findings are discussed in the **Federal Register** of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300) and the section 4(a)(1)(B) findings are discussed in the **Federal Register** of June 5, 1981 (46 FR 30302).

In evaluating the ITC's testing recommendations concerning BPA, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of BPA under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) concerning BPA; and published and unpublished data available to the Agency. Based on its evaluation, as described in this proposed rule, EPA is proposing health and environmental effects testing requirements for BPA under section 4(a)(1)(A). By these actions, EPA is responding to the ITC's designation of BPA for priority testing consideration.

C. Change in Process for Adopting Test Standards

EPA announced an approach to adopting test rules that involved two-phase rulemaking in the **Federal Register** of March 26, 1982 (47 FR 13012). In the first phase of rulemaking, EPA would specify the test substance, who would be responsible for testing, and the required tests. In the second phase, EPA would establish the test methodologies (test standards) and the deadlines for submission of test data. EPA has used this approach for most of the test rules it has proposed for chemicals designated in the first through the thirteenth ITC reports.

In December 1983 the Natural Resources Defense Council (NRDC) and the Industrial Union Department of the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) filed an action under TSCA section 20 which challenged, among other things, the use of the two-phase process. In an August 23, 1984 Opinion and Order, the Court found that utilization of the two-phase rulemaking process was permissible. However, the Court also held that the Agency was subject to a standard of promulgating test rules within a reasonable time frame. (*NRDC* and *AFL-CIO* v. *EPA*, 595 F. Supp. 1255 (S.D.N.Y.)).

Subsequent to the issuance of this Opinion, the Agency submitted papers to the Court which indicated that in order to expedite the test rule development process, EPA would utilize a single-phase rulemaking process for most test rules. The Agency also indicated that EPA would publicly announce this policy in the first test rule proposal to be published in the spring of 1985. (Declaration of Don R. Clay, at 12 (September 24, 1984)). In accordance with this commitment, the Agency is setting forth in the preamble of this proposed rule and elsewhere in today's **Federal Register** notice, guidelines and procedures for utilization of single-phase rulemaking in the test rules program.

Section 4(b)(1) specifies that test rules shall include standards for the development of test data ("test standards") and deadlines for submission of test data. Under the two-

phase process, both test standards and data submission deadlines are established during the second phase of rulemaking. However, in the single-phase approach, EPA will propose the pertinent OTS test guideline(s) or other suitable test guideline(s) as the required test standards in the initial notice of proposed rulemaking, and EPA will also propose time frames for the submission of the test data. Industry and other commenters may suggest an alternative methodology or modifications to the OTS guideline, i.e., the proposed test standard, during the public comment period, and such comments should state why the alternative methodology or modification is more suitable for the chemical substance in question than the EPA-proposed test standard. Comment will also be sought on the proposed data submission deadlines. All such submissions, including alternative test methodologies, will be placed in the rulemaking record and will be available for review by the public. The final rule will promulgate as the test standards either the OTS guidelines or other suitable guidelines, a modified version of these guidelines, an alternative methodology submitted in comments, or a modified version of the alternative methodology. The proposed test standards and data submission deadlines will be open for discussion at any public meeting held pursuant to TSCA section 4(b)(5).

The single-phase approach offers a number of advantages over the two-phase approach. First, the Agency believes that the single-phase approach will shorten rulemaking, resulting in the expedited initiation of the required testing. Secondly, because the OTS guidelines or other appropriate methodologies will be proposed as the test standards, the one-phase process eliminates the requirement under the two-phase approach for industry to submit test protocols for approval. Yet, by allowing submission of alternative test methodologies during the comment period, it preserves the flexibility of the two-phase process, but at reduced administrative cost.

Because of these advantages, the Agency intends to utilize single-phase rulemaking for most rules promulgated under TSCA section 4(a). However, EPA will continue to utilize the two-phase process for rulemakings where the two-phase process may be a more expeditious route to a final test rule, e.g., in cases where no well-accepted test methodology is available for inclusion in a proposed test rule.

II. Bisphenol A

A. Profile

BPA is a white solid with a mild phenolic odor. Depending on purity, its melting point ranges between 153 °C and 157 °C (Ref. 1). It has a rather low vapor pressure at ambient temperatures, but it can be distilled at 220 °C at 4 mm Hg (Ref. 2). EPA has calculated its solubility in water to be 120 mg/1 at 25 °C. BPA is soluble in polar organic solvents, and various octanol/water partition coefficients have been reported from several sources to be 3.32 (Ref. 3) and 2.20 (Ref. 4) as experimentally determined log K_{ow} values, and 3.84 (Ref. 5) as a calculated log K_{ow} value.

By applying these data to the EPA ENPART model the environmental distribution of BPA can be estimated. Using the relative volumes of the water, soil, and air compartments built into the ENPART model, the mass environmental distribution of BPA is 96 percent in water, 4 percent in soil, and a trace in air. Based on partitioning data, estimated rates of hydrolysis, photolysis and biodegradation, and inter-media transport rates, the environmental persistence from the steady state condition after loading ceases is approximately 90 years for a 50 percent mass reduction.

B. Production

In the commercial process for producing BPA, phenol and acetone are charged to a glass-lined reactor, in a molar ratio of two or three to one. Dry hydrogen chloride, as the catalyst, is bubbled through the mixture, which is kept at about 50°C for 8 to 12 hours. Careful control is necessary to prevent a number of side reactions which would yield impurities.

The product slurry is then washed with water, neutralized, and distilled under vacuum to remove water and phenol. The BPA, which is still molten, is then sprayed with steam to remove traces of methyl mercaptan, which was added initially as a catalyst promoter, quenched in water, washed, filtered and dried. More recently, the purification process has been carried out continuously, using distillation and extractive crystallization. For BPA to be used as a polycarbonate feedstock, an additional purification step is necessary to remove all BPA isomers (Refs. 6 and 7).

The manufacturers of BPA have included Dow Chemical USA, General Electric (GE), Shell Chemical, Union Carbide, and USS Chemicals. Union Carbide put its facility on standby in 1982 and has not announced plans for resuming production. Thus, four companies are current producers. Shell reportedly planned to increase its capacity in its existing plant during 1984 (Ref. 7).

All of these companies have captive on-site or nearby sources of the BPA feedstocks, phenol and acetone. All of the companies, except USS Chemicals, also use much or all of their production captively. Dow, GE, and Shell produce the necessary coreactants for their epoxy and polycarbonate derivatives which are downstream products of BPA. Although it currently sells BPA only in the merchant market, USS Chemicals is considering the construction of a polycarbonate plant (Ref. 7).

BPA production grew at annual rates of 15 percent in the 1960's and then ten percent in the 1970's. After reaching a peak of 576 million pounds in 1979, production fell to 480 million in 1982, due to the general recession and a major decline in exports. In 1983, production reportedly rose past the 1979 peak to 643 million pounds, due to recovery in the construction, automobile, appliance and electronics industries (Ref. 7). Preliminary figures through October 1984 indicate a further significant increase. If the ten month trend continued through year end, BPA production in 1984 would be up 22 percent to 785 million pounds. Imports of BPA have been minor. Exports were about 40 million pounds per year in the early 1980's (Ref. 7).

C. USE

Domestically, BPA is used in the manufacture of polycarbonate resins (50 percent of manufactured BPA), epoxy resins (44 percent), polysulfone and phenoxy resins (2 percent), and miscellaneous products (4 percent) (Ref. 7).

Polycarbonates are linear polyesters of carbonic acid. The principal commercial polycarbonate (PC) is formed from BPA and phosgene ($COCl_2$). The dominant commercial process for making PC uses a batch-wise direct reaction of the feedstocks in aqueous sodium hydroxide, with a small amount of phenol added to control the chain length. The resulting polymer dissolves across a liquid-liquid interface into an immiscible methylene chloride phase in the reactor. When the reaction is complete, the phases are separated and the PC is purified (Ref. 7).

The two domestic producers of PC are the General Electric Co., Plastics Business Operations, with 300 million pounds of capacity in Mount Vernon, IN, and the Plastics and Coatings Division of Mobay Chemical Corp. (a Bayer subsidiary), with 130 million pounds of

capacity in Cedar Bayou, TX (Ref. 7). Dow Chemical Co. has been operating a ten million pound per year pilot plant in Freeport, TX, for several years. It plans to bring a 30 million pound plant on-line in the first quarter of 1985, with a duplicate unit to follow later (Ref. 7).

The principal end-use categories of PC plastics are glazing, communication and electronics equipment, appliances, sports equipment, transportation equipment, lighting, and signs.

Epoxy resins are the other major use of BPA. Epoxies are a class of thermosetting resins with versatile composition and superior toughness, adhesion, heat and chemical resistance, and electrical properties. They are generically polyethers with terminal, and sometimes side-chain, epoxy groups. The dominant epoxy is formed by the reaction of epichlorohydrin and bisphenol A.

The epoxy resins are manufactured in several steps which involve BPA in different ways. The common practice uses the direct reaction of an excess of epichlorohydrin with BPA in an alkaline solution to give crude epoxy. Such products are known as unmodified epoxies.

The advancement process is commonly used to achieve higher molecular weight resins. BPA is added to crude epoxy produced above, in the presence of a catalyst. Comonomers such as flame-retardants, can also be added, either directly or as a prepolymer (reaction product) with the BPA or crude expoxy (Ref. 7). The resulting materials are known as advanced, or modified, epoxies. In the final uses, a curing agent (anhydride, aliphatic amine, polyamide, or one of a variety of others) is added to form cross-linkages among the hydroxy groups and terminal epoxides (or a catalyst promotes self-polymerization), causing the epoxy to harden and form its final properties (Ref. 7). Thus, in much of their use, epoxy resins are more strictly a chemical intermediate, rather than a final end-use resin as is the case for PC (Ref. 7).

Unmodified BPA-epoxies are produced in the United States by five major companies at eight locations. The companies, and their capacities for both unmodified and advanced BPA-epoxies (thus double-counting some BPA demand), are (in millions of pounds): Celanese Corp. (30); Ciba-Geigy Corp. (70); Dow (230); Reichhold Chemicals (32); and Shell (270), for total capacity of 632 million pounds. Two-thirds to three-fourths of this capacity is for liquid BPA-epoxy resins. A dozen other companies also report the production of unmodified BPA-epoxies. Advanced or modified BPA-epoxies are made by 30 to 40 companies, including major paint, electronics, and adhesives companies (Ref. 7).

The principal uses of BPA-epoxy resins are for coatings, laminates and composites, castings and molded items, flooring and construction materials (Ref. 7).

BPA is used as a basic component of a variety of other plastic resins. The most important is polysulfone, which is a thermoplastic polymer produced by condensing BPA with 4,4'-dichlorophenylsulfone. With U.S. production estimated at 15 million pounds in 1982, polysulfone consumes about one percent of BPA (Ref. 7).

Polysulfone is used as a specialty engineering plastic to make power-tool housings, medical and electrical equipment, electronic and computer components such as printed circuit boards, professional food processing equipment, and extruded pipe, pressure valves, distillation tower components and other chemical processing equipment.

D. Exposure and Release

The National Occupational Hazard Survey (NOHS) data base (Ref. 8) estimates that as many as 33,000 people in the chemical industries may be exposed to BPA at 911 plants. The National Occupational Exposure Survey (NOES) data base (Ref. 9) estimates that 9,446 workers (of whom 1,541 are female) are exposed to BPA. Whereas the NOHS data base uses actual exposures, exposure to tradename products thought to contain BPA, and exposures to products of the type that contain BPA, the NOES data base is limited to workers present where BPA has been identified to be present.

During production of the flaked BPA, there are fugitive air emissions associated with packaging and bulk loading operations. Plant monitoring studies show BPA average air concentrations ranging from less than 0.01 to 5.7 mg/m^3 (Ref. 10). The particle size of 99 percent of the packaged BPA is greater than 100 mesh (147 microns). BPA dust in 3 samples of the packaged product from one company had a particle size distribution ranging from 81.2 to 90.5 percent for mesh size less than 20, 8.8 to 17.2 percent for mesh sizes 20–100, and 0.7 to 1.6 percent for mesh sizes greater than 100. Additionally, estimation of particle sizes for 2 samples of airborne dust collected during packaging of flaked BPA indicated less than 30 and 14 percent of the estimated BPA dust by weight was less than 10 microns in size (Ref. 10).

Dow Chemical reported BPA dust present in work stations handling flaked product at levels between 0.3 and 2.6 mg/m^3 for extended monitoring periods and between 2.3 and 3.4 mg/m^3 during shorter periods (Ref. 11). Plant area monitoring studies showed daily levels between 0.4 to 6.8 mg/m^3 (Ref. 11).

Only one reference to BPA in envirionmental samples in the U.S. has been found (Ref. 12). This sample was actually an effluent from a plant in Mt. Vernon, IN., rather than a true environmental matrix. Neither the analytical method used nor the concentration of BPA found was reported. No other monitoring surveys detecting BPA in U.S. waters are known.

There are two reports of BPA contamination of the environment in Japan. Matsumoto and Hanya (Ref. 13) found BPA amount the phenolic and carboxylic compounds in atmospheric fallout near Tokyo. Deposition rates for BPA ranged from 0.04 to 0.2 $\mu g/m^2$ per day, compared to total phenolics that ranged from 1.5 to 12 $\mu g/m^2$ per day, and total organic carbon that averaged 12,000 $\mu g/m^2$ per day. BPA was not found in surface soil.

BPA was also found at low levels in river water sediments (Ref. 14). In two out of three samples from the Tama River in Japan taken during 1973, it was not detected, and in the third sample, it was detected in the range of 10 to 90 ng/1. The authors concluded that the BPA was probably from an industrial source.

Domestically, Shell Chemical determined the amount of BPA in plant wastewater effluents at its Deer Park, TX., facility to be 0.08 ppm or less on three sampling days (Ref. 15). A second company measured BPA levels in production/processing wastewater effluents at less than 0.1 ppm for three consecutive days. A third company's wastewater effluent concentration of BPA was described as typically less than 0.1 ppm (Ref. 10). Another company has detected no BPA at levels greater than 40 ppb in sampling wells around a landfill for BPA wastes.

The manufacturers believe that polycarbonates and cured epoxy resins are insoluble in water and most solvents, and non-biodegradable, and because of their long life applications, resistant to degradation. Furthermore, any unreacted BPA in the resin is expected to remain encapsulated in the polymer.

Thus, consumer and general population exposure to BPA also is not expected to be very significant. To prove this point, extraction studies were carried out on molded polycarbonates using various digestion precedures. No BPA was detected in washings (Ref. 10).

At BPA manufacturing and major processing facilities, production is continuous and continuous biotreatment wastwater systems are used. One company produces and processes BPA, both via continuous processes. At this facility BPA is a component of several waste streams which go to disposal. These streams are liquid organic mixtures (50 percent BPA), dry solids (i.e., sweeping, small spills) (95 to 100 percent BPA), and wet solids (i.e., sumps, etc.) (70 percent BPA) (Ref. 10).

The liquid organic waste streams are incinerated on site and the dry solid wastes are currently sent to a commercial hazardous waste facility. Some of the dry solid wastes and all of the wet solid wastes are periodically dumped into a primary solids lagoon. The pH of the lagoon is maintanied at 10 to ensure solubility of the BPA. The decant water from the lagoon, containing 20 to 70 ppm BPA salts, is sent to a neutralizing distributor box. The content of the outflow of the distributor box is 4 to 10 ppm BPA. Further dilution with other streams reduces BPA content to 0.2 to 0.5 ppm. The usual aeration in activated sludge, followed by clarification, reduces the BPA to less than 0.1 ppm in the outfall from the plant. The analysis of three outfall samples resulted in two values described as non-detectable and one value of 0.08 ppm; the detectability limit is 0.05 ppm (Ref. 10).

Another company which maufacturers and processes BPA uses a similar biotreatment process. The influent to the system averaged 0.2 ppm and the effluent was less than 0.01 ppm on three consecutive days (Ref. 10).

A third company which also manufactures and processes BPA uses a similar biological effluent treatment system. Input to the system contains 5 to 10 ppm of BPA; outfall from this plant averages 0.1 ppm of BPA (Ref. 10).

E. Environmental Fate and Effects

BPA can enter the environment as dust or in wastewaters. Its low vapor pressure (0.20 mm Hg at 170 °C; Ref. 2), moderate solubility in water, and moderate octanol/water partition coefficient (experimentally determined log P=3.32 and 2.20, and calculated log P=3.84; Refs. 3, 4 and 5) indicate that BPA should partition mainly to water as opposed to soil and air. BPA is not expected to bioconcentrate significantly in aquatic animals because of its moderately low water solubility and partition coefficient. The bioconcentration factors calculated using the available log K_{ow} values are 133 (based on log K_{ow} 3.32), 15 (2.20), and 366 (3.84) (Ref. 16).

Photo-oxidation of BPA in surface water is likely based on analogy with other phenols (Ref. 17). BPA was easily decomposed by test-activated sludge in wastewater (Ref. 18). BPA and phenol were decomposed by *Chlorella vulgaris* and *Scenedesmus obliquus* in laboratory experiments (Ref. 19). Studies from Dow Chemical Company also indicate that BPA will be degraded by acclimated cultures (Ref. 20). The biochemical oxygen demand (BOD) reported at 5 days (BOD_5) was 26 percent of the theoretical oxygen demand; the BOD_5 and BOD_{20} were 56 and 71 percent, respectively.

However, the rate of BPA degradation by fresh mixed microbial cultures is much lower. Using widely accepted test methods for determining a chemical's "ready biodegradability," Shell Chemical Company produced test data indicating that BPA does not readily biodegrade (Ref. 21). In a Closed Bottle Test (procedure described in OECD test guidelines 301D), BPA consumed none of its theoretical oxygen demand in 28 days from an initial test concentration of 3 ppm, nor did it significantly inhibit the test system. Using the Modified Sturm test only 1 to 2 percent of BPA's theoretical carbon dioxide production was observed in 28 days based on an initial test concentration of 20 ppm. BPA also inhibited the growth of *Pseudomonas fluorescens* with an IC_{50} of 54.5 mg/l (Ref. 21).

There was little information in the available literature on the environmental effects of BPA. Polozova *et al.* (Ref. 22) reported that BPA completely inhibited the growth of the fungus *Septoria avenae* at a concentration of 0.1 percent in culture media. BPA was mixed with agar in Petri dishes at concentrations of 0.0, 0.005, 0.01, 0.02, 0.03, 0.1, 0.2, and 0.5 percent, the fungi inoculated, and the cultures incubated for 5 days. However, additional information on the methods, incubation conditions, and number of replicates used was not reported. The effects of BPA on peroxidase and catalase activities, and ascorbic acid and gluten content in wheat plants, as well as its effects on some sugars and amino acids in black currants were reported (Ref. 23). The data suggest that at low concentrations, BPA had favorable effects on plant growth and yield.

Dow Chemical Company (Ref. 24) reported that the 96-hour LC_{50} value for BPA to the sheepshead minnow, *Cyprinodon Variegatus*, in flow-through experiments was 7.5 ppm. The tests utilized 10 fish per group, each weighing approximately 1.3 g, maintained at 80 °F. The report, however, does not describe the analytical results of the study, responses observed at other concentrations, nor the stability of the compound in the stock solution.

Other aquatic toxicity data made available to the Agency through the BPA manufacturers include a 96-hour LC_{50} nominal value of 4–6 ppm for the Lake Emerald shiner (Ref. 25), a 96-hour LC_{50} nominal value of 3–3.5 ppm for the rainbow trout, *Salmo gairdneri* (Ref. 26), a 48-hour LC_{50} nominal value of 3.9 ppm for *Daphnia magna* (Ref. 27), and a 96-hour EC_{50} nominal value of 2.5 ppm for *Selenastrum capricornutum* (Ref. 27).

F. Findings for Environmental Fate and Effects

The Agency finds that sufficient data are available from testing done by Shell Chemical Co. and Dow chemical Co. to reasonably predict BPA's persistence in the environment.

The Agency also finds that sufficient data are available on BPA's octanol/water partition coefficient from values calculated and experimentally derived. EPA believes that additional testing would probably serve only to confirm that the log k_{ow} for BPA lies between 3.3 to 3.8, and within that range closer to the 3.3 value. This is because the method used by Thorp (Ref. 4) for experimentally determining BPA's log k_{ow} of 2.2 is only expected by EPA to give a value within ±1 log unit of the "true" experimental value. The value of 2.2 is nearly 1 log unit from the 3.3 to 3.8 range. The Agency believes that by using this information sufficient data are available on the octanol/water partition coeffecient to reasonably predict BPA's ability to bioconcentrate.

After reviewing and evaluating the existing aquatic acute toxicity data for the BPA, EPA has determined that they are not reliable because the concentrations reported in most studies are not measured and where they are, the results are not completely described. Therefore, these data are insufficient to accurately quantify the levels of acute toxicity and to reasonably predict the chronic effects levels of BPA. These data are sufficient, however, to indicate that BPA may be toxic to sensitive aquatic species at less than 1 ppm. The Agency believes that data on other compounds have demonstrated that if a compound is not acutely toxic to aquatic organisms at less than or equal to 1 ppm, it is not likely to cause chronic effects at the ppb levels (i.e., the levels at which EPA has determined from confidential business information that BPA may be found in the environment). Conversely, data have shown that compounds with LC_{50}s less than 1 ppm ofter have chronic

effects at levels in which BPA may be found in the environment. The Agency finds that BPA may present an unreasonable risk of acute and chronic aquatic toxicity, that data are insufficient to reasonably determine or predict these effects as a result of manufacturing and processing, and that testing is necessary to develop such data. EPA is therefore proposing that acute aquatic toxicity testing be conducted to determine the sensitivity of freshwater and marine algae, invertebrates and fish to BPA under TSCA section 4 (a)(1)(A).

EPA is also proposing that if the LC_{50} value derived from any of the invertebrate or veratebrate acute tests is less than 1.0 ppm, or there are indications of chronicity (i.e., the ratio of the 48-hour to 96-Hour LC_{50}s greater than 2), then chronic toxicity tests with the most sensitive vertebrate or invertebrate species shall be performed. If neither or the above criteria is met, the Agency believes that chronic aquatic toxicity testing is not needed.

Consequently, the Agency is proposing that acute toxicity testing of the aquatic species listed in Unit II.I. using the OTS Test Guidelines shall be required. Upon completion of these studies, the results shall be evaluated to determine if they meet the criteria described above indicating the likelihood of chronic effects occurring at ppb levels. If the criteria are met, cnronic toxicity tests with the most sensitive test species shall be automatically required through finalization of this proposed rule for BPA.

G. Health Effects

1. *Metabolism.* BPA is absorbed from the gastrointestinal tract after oral administration. Experiments conducted by Knaak and Sullivan (Ref. 29) showed that in rats 56 percent of the radioactivity of an orally administered dose of 120 mg of BPA was excreted via feces and 28 percent via urine. Less than 1 percent of metabolities in urine were present as free BPA, while 88 percent appeared as glucuronide conjugate. In feces, 35 percent was excreted as free BPA, 35 percent as hydroxylated BPA, and 30 percent unidentified.

2. *Acute toxicity.* Acute toxicity studies of BPA resulted in LD_{50} values ranging between 3,250 and 5,660 mg/kg when given orally to rats (Refs. 2 and 28). The oral LD_{50}s for mice and rabbits were 2,500 and 2,230 mg/kg, respectively (Ref. 28). BPA also showed eye- and skin-irritating properties.

A 14-day repeated dose study was performed as part of the National Toxicology Program's (NTP) range-finding activities for the subchronic testing of BPA (Ref. 30). Groups of five males and five females of each species (Fischer-344 rats or B6C3F1 mice) were administered BPA in their diet for 2 weeks at concentrations of 0, 300, 1,000, 2,500, 5,000, or 10,000 ppm. No deaths occurred in either rats or mice. However, mean body weight gain in male rats was decreased by 60 percent or more, as compared to that of the controls, at doses of 2,500 ppm or more. Doses of 5,000 ppm or more produced a decrease in body weight gain averaging 40 percent in female rats. Body weight changes in male and female mice at all dose levels were comparable to those of the control group.

3. *Subchronic toxicity.* To determine suitable dosage levels of BPA to be used in oncogenicity studies, the NTP performed a 90-day study on rats and mice (Ref. 30.). Groups of 10 animals per sex of Fisher-344 rats were given 0, 250, 500, 1,000, 2,000, or 4,000 ppm of BPA in their diet for 13 weeks. Two of the ten male rats that received 1,000 ppm of BPA died. The time of death was not reported. Although food consumption was not changed at any dose level, weight gain in males and females that received 1,000 ppm or more of BPA was depressed by 18 percent and 10 percent, respectively. Hyaline masses were found in the urinary bladder lumen of 30–60 percent of all dosed male animals. A compound related cecal enlargement was also found in 60–100 percent of animals in all dosed groups except female rats that received 250 ppm. No abnormalities were detected when cecal walls were examined histologically.

In the same study (Ref. 30), groups of B6C3F1 mice (10 per sex) were fed BPA in concentrations of 0, 5,000, 10,000, 15,000, 20,000, or 25,000 ppm in diet for 13 weeks. Two female animals from the group that received the lowest dose of BPA (5,000 ppm) died. Body weight gain was decreased by 14 percent or more in male mice that received 15,000 ppm or more and in females of all groups. Multinucleated giant hepatocytes were also observed to be dose related in male mice.

Stasenkova *et al.* (Ref. 31) administered BPA to rats by inhalation ("dynamic method," otherwise unspecified) at concentrations approximately those of workroom atmospheres (i.e., about 50 mg/m^3, an average of 47 mg/m^3 with a range of 15–86 mg/m^3 for 4 hours/day for 4 months. Whether it was for 5 or 7 days a week was not clear. By the end of the fourth month, there were "pronounced signs of intoxication." Body-weight gain was depressed in exposed animals relative to controls (89 percent *v.* 107 percent); synthesis of hippuric acid was likewise depressed (92 mg in exposed *v.* 128 mg in control); the ascorbic-acid content of the exposed group was decreased compared to controls in the liver and kidney (20.1 and 34.6 mg, respectively, *v.* 23.5 and 41.1 mg in controls). The relative organ weights of liver and kidney were increased relative to controls (4.2 and 0.81, respectively, compared with 3.5 and 0.73 in the controls). These differences were all reported to be statistically significant. Histological signs of intoxication included a slight "plethora" of the liver, "protein swelling of cells" in the kidney, and a thickening of interalveolar partitions. The authors reported that all toxic changes had resolved within 1 month after cessation of exposure.

4. *Oncogenicity.* The NTP oncogenicity bioassay of BPA (98 percent pure) was conducted by feeding diets containing 1,000 (equivalent to 74 mg/kg/day) or 2,000 ppm (equivalent to 148 mg/kg/day for male and 135 mg/kg/day for female rats) of the compound to groups of 50 Fischer-344 rats of either sex, 1,000 or 5,000 ppm to groups of 50 male B6C3F1 mice and 5,000 or 10,000 ppm to groups of 50 female B6C3F1 mice for 103 weeks (Ref. 30). Groups of 50 rats and 50 mice of each sex served as controls.

In rats, the survival was the same for treated and untreated animals up to 65 weeks. Beyond this time the percent of survival began to decline. In male rats, the control group had the lowest survival, and the low-dose group had the highest survival. The low-dose group consistently maintained a 5 to 10 percent higher rate of survival than the control (no explanation was given). In the female rats, the survival was essentially the same for the control and two treated groups.

In mice, the controls had a higher survival than those treated in both sexes. All the mean body weights of the treated animals were lower than the controls except the male mice on the low dose diet. The food consumption of the dosed male rats was 90 percent that of the controls, and that of the dosed female rats was only 70–80 percent that of the controls. The data on food consumption of mice were incomplete due to spilling, but the investigators considered it to be similar among all groups of mice. Major tissues were examined grossly and microscopically.

Leukemia occurred at increased incidences in dosed rats of both sexes and in dosed male mice. In male rats, the dose-related trend was 13/50 (controls), 12/50, and 23/50.

The incidences of leukemia in female rats were 7/50 (controls), 13/50, and 12/50. In male mice the combined incidence of leukemias and lymphomas was 2/49, 9/50, and 5/50. However, these effects were not considered by NTP to be compound related effects. Interstitial-cell tumors of the testes occurred in low- and high-dose male rats; however, the increased incidence observed in this study (35/49, 48/50, 46/49) was not considered compound-related because this lesion normally occurs at a high incidence in aging Fischer-344 male rats.

5. *Mutagenicity.* The mutagenic potential of BPA was tested by NIOSH in *Salmonella typhimurium* strains with and without activation (Ref. 23). The compound was not mutagenic in these tests. These results were later confirmed by NTP testing in *Salmonella* (Ref. 23). A separate study (Ref. 23) reported that BPA had no effect on somatic cells of *Drosophila melanogaster.* Dominant lethal tests on rats and sperm abnormality tests in mice were also negative for BPA (ref. 32).

6. *Developmental toxicity.* The developmental toxicity (teratogenic) potential of BPA was studied using young adult female Sprague-Dawley rats (Ref. 33). BPA dissolved in corn oil was injected intraperitoneally on day 1 through day 15 of gestation. Doses used were 85 mg/kg (0.37 mmol/kg, the 5-day maximum tolerated dose (MTD) for male rats in a dominant lethal study (Ref. 32)), and 125 mg/kg (0.55 mmol/kg, the MTD in this study).

A significant decrease in the mating index (number pregnant per number mated × 100) was observed in animals that received the high dose level (3 of 12; 25 percent) as compared to that of the control (11 of 12; 91.7 percent). The mating index of the animals in the low dose group was 100 percent; however, only 4 animals were used, compared to 12 in the control and high dose groups. Both dose levels decreased the number of live fetuses and the number of implants per litter. The significant decrease in the mating index of rats that received the 125 mg/kg dose was ascribed to an estrogenic effect of bisphenol A resulting in blockage of implantation.

Fetal toxicity included significant decreases in fetal body weights and crown-rump length, which were observed at both dose levels used.

Although the number of litters in the treated groups was limited, several significant changes were found in the treated groups when compared to those in the control group. These changes included enlarged cerebral ventricles (in both dose levels), incomplete skeletal ossification (in both dose levels) and hydrocephaly (in the 125 mg/kg group). Imperforate anus was also observed in three fetuses from a single litter that received 125 mg/kg of BPA.

An NTP teratology study on rats and mice that received BPA orally is in progress; the study protocol is available for review in the public docket for this rule (docket no. OPTS-42069).

7. *Reproductive effects.* Ovariectomized adult Sprague-Dawley rats injected intraperitoneally with a single dose of 50 or 100 mg/kg of BPA showed a significant increase in the percentage of uterine weight (Ref. 33). In the same study, doses of 85 mg/kg per day of BPA injected intraperitoneally for 5 consecutive days to adult male Sprague-Dawley rats and adult male C3H/He mice failed to show an effect in a dominant lethal study (rats) or produce evidence of sperm abnormality (mice).

Reproductive effects testing sponsored by GE in which BPA was fed in the diet of Charles River CD® rats for 17 weeks (F_0 generation) and for 13 weeks (F_1 generation) at 1,000, 3,000, and 9,000 ppm produced no compound-related effects in the fertility indices, number of pups per litter, or pup survival (Ref. 34). Decreased body gains were the only observed effects in either generation of rats.

In a followup reproductive effects study (Ref. 34), using BPA dietary levels of 100, 250, 500, 750, and 1,000 ppm, no differences were seen in F_0 female estrus cycles, male and female fertility indices, length of gestation period, number of pups per litter, or pup body weights.

NTP is completing a continuous breeding BPA reproductive effects study in mice. The test protocol for this study is available for review in the public record for this notice. Final study results should be available in mid-1985.

H. Findings for Health Effects

EPA finds that sufficient data are available from the NTP bioassay report to reasonably predict that ingested BPA is not oncogenic. EPA therefore accepts NTP's conclusion that the ingestion carcinogenicity study results give no convincing evidence that BPA was carcinogenic to laboratory animals under the conditions of study. There also is no reason at this time to believe that inhalation of BPA, as suggested by the ITC, would present any greater oncogenic potential than ingestion. Differences in metabolism when BPA is ingested versus inhaled are not expected to be significant. Therefore, BPA is not expected to be any more active in producing tumors via inhalation than via ingestion.

The Agency also finds that additional reproductive effects testing is underway at NTP. EPA believes that when considered in conjunction with available industry testing of reproductive effects, sufficient data are available to reasonably predict BPA's reproductive effects potential in humans.

EPA believes appropriate developmental toxicity testing has been conducted at NTP. Preliminary study results indicate that the final reports should provide sufficient data to reasonably predict BPA's teratogenic potential.

EPA believes, however, that insufficient data are available to reasonably predict BPA's localized effect on lung tissue after chronic inhalation exposure, which is the most likely route of workplace exposures. Available monitoring data indicate that in a large portion of the workplace environments BPA dust is readily available for inhalation because of its respirable size. The BPA manufacturers have also supplied information showing that workers have registered compliants of eye, nose, and throat irritation when exposed to this dust at levels equal to OSHA's 8-hr. time weighted average (TWA) workplace nuisance dust limit of 5 mg/m^3.

Therefore, because of this information, the fact that several hundred to 9,500 workers may be exposed to BPA dusts, and the findings of one study which describes observable changes in lung tissues of rats after extended inhalation exposures to BPA, the Agency finds that: (1) Subchronic inhalation exposures to BPA may present an unreasonable risk of lung injury to workers involved in the manufacture and processing of BPA; (2) there are insufficient data to reasonably determine or predict the risk of injury to the lungs from subchronic inhalation of BPA; and (3), testing is necessary to develop such data. EPA is proposing under TSCA section 4(a)(1)(A) that manufacturers and processors of BPA conduct a 90-day subchronic dust inhalation toxicity study in rats, including a 21 to 35 day post-exposure recovery and observation period, to characterize the effects of BPA dust on lung tissues.

There is no information currently available that raises concern for other health effects of BPA.

I. Proposed Testing and Test Standards

On the basis of the findings given above for environmental fate and effects testing (Unit II.F.), the Agency is proposing that acute aquatic toxicity testing of BPA shall be conducted on (1)

the freshwater alga, *Selenastrum capricornutum*, and the saltwater alga, *Skeletonema costatum*, using the OTS test guideline entitled "Algal Acute Toxicity Test" (EG–8), (2) the freshwater invertebrate, *Daphnia magna*, using the OTS test guideline entitled "Daphnid Acute Toxicity Test" (EG–1), (3) the saltwater invertebrate, *Mysidopsis bahia*, using the OTS test guideline entitled "Mysid Shrimp Acute Toxicity Test" (EG–3), (4) the freshwater vertebrate, *Pimephales promelas* (fathead minnow), using the OTS test guideline entitled "Fish Acute Toxicity Test" (EG–9), and (5) the saltwater vertebrate, *Menidia peninsulae*, using the "Flow-Through Methods for Acute Toxicity Tests Using Fishes and Macroinvertebrates" given in an EPA published document entitled "Bioassay Procedures for the Ocean Disposal Permit Program".

The Agency also is proposing that if the 96-hour LC_{50} value from any of the vertebrate or invertebrate acute test species is less than 1.0 ppm, or there are indications of chronicity (i.e., the ratio of the 48-hour to 96-hour LC_{50}s is greater than 2), then chronic toxicity testing with the most sensitive (i.e., that with the lowest LC_{50} value or in the absence of an LC_{50} lower than 1 ppm the test species that showed the greater tendency for chronicity) vertebrate or invertebrate species shall be performed. Where one of the above criteria for chronic testing is met for any of the vertebrate or invertebrate acute test species, chronic testing shall be conducted on either (1) Daphnia using the OTS test guideline entitled "Daphnid Chronic Toxicity Test" (EG–2) or Mysid using the OTS test guideline entitled "Mysid Shrimp Chronic Toxicity Testing" (EG–4), or (2) fathead minnow using the OTS test guidelines entitled "Fish Early Life Stage Toxicity Test" (EG–11) or *Menidia* using the procedures of Goodman *et al.* (Ref. 35). EPA is proposing that if nether criterion is met for any of the four required invertebrate and vertebrate acute toxicity test species, no chronic toxicity test shall be required.

The Agency is proposing that the above referenced OTS Environmental Effects Test Guidelines and other cited methods be considered the test standards for the purposes of the proposed test for BPA. The OTS guidelines for aquatic toxicity testing specify generally accepted minimal conditions for determining aquatic plant and animal toxicities for substances like BPA to which aquatic life is expected to be exposed. The Agency's review of the guidelines, which occurs on a yearly basis according to the process described in 47 FR 41857 (September 22, 1982), has found no reason to conclude that these protocols need to be modified significantly. Additionally, the "Bioassay Procedures for the Ocean Disposal Permit Program" and the test procedures employed by Goodman *et al.* (Ref. 35) specify, in EPA's judgement, minimal test conditions and practices for acceptable investigation of BPA's acute and chronic toxicities to the saltwater vertebrate, *Menidia peninsulae*. Although the Agency has not issued OTS testing guidelines for saltwater vertebrates, the testing procedures found in these references reflect the current state-of-the-art for such testing and are being proposed as acceptable methods of testing BPA in a saltwater fish.

On the basis of the findings given above for health effects testing (Unit II. H), the Agency is proposing that a 90-day subchronic inhalation toxicity test with a 21 to 35 day post-exposure recovery and observation period shall be conducted for BPA.

EPA is proposing that this testing be done in accordance with the procedures given in the OTS Health Effects Test Guideline entitled "HG-Subchronic-Inhal 1983" which reflects current standards among toxicologists for obtaining reliable data on effects that might occur during and immediately after subchronic exposure to a substance via inhalation. The guideline specifies generally accepted minimal conditions for determining a no-observed-effect-level for substances like BPA to which people are expected to be exposed repeatedly over a limited period of time. The Agency has not received any new data since the last revision in 1983 (48 FR 44898) which would justify a major reappraisal of the guideline. The Agency reviews its OTS test guidelines once a year according to the process described in the **Federal Register** of September 22, 1982 (47 FR 41857), and has found no reason to indicate that this guideline needs to be modified significantly. Therefore, EPA is proposing that this guideline be considered the test standard for the purposes of the proposed subchronic inhalation test for BPA.

Certain modifications and clarifications of the subchronic inhalation test guideline have been included in the proposed test standard for this substance. They reflect the Agency's particular concern with the respiratory system after exposure to BPA via inhalation.

J. Test Substance

EPA is proposing that BPA of at least 95 percent purity be used as the test substance: EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to BPA itself. Commercial BPA ranges in purity from 92 to 99 percent (Ref. 36).

K. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the manufacture and processing of BPA may present an unreasonable risk to human health and the environment, EPA is proposing that persons who manufacture or process, or intend to manufacture or process BPA at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the aquatic toxicity testing and subchronic toxicity testing requirements contained in this proposed rule. The end of the reimbursement period is proposed to be 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement.

EPA promulgated procedures for applying for TSCA section 4(c) exemptions for use with two-phase rulemaking published in the **Federal Register** of October 10, 1984 (49 FR 39774). Elsewhere in today's **Federal Register**, EPA is issuing an interim final exemption policy for use with single-phase rulemaking. Procedurally, these differ only slighty from those previously adopted. In brief, when both manufacturers and processors are

subject to a test rule, processors will be granted an exemption automatically without filing applications if manufacturers perform all of the required testing. Manufacturers are required to submit either a letter of intent to perform testing or an exemption application.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for BPA. As noted in Unit II.J, EPA is interested in evaluating the effects attributable to BPA itself and has specified a relatively pure substance for testing.

L. Study Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its final TSCA GLP standards which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 792 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans within 30 days before initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The aquatic vertebrate, invertebrate and algal acute toxicity tests shall be completed and the final results submitted to the Agency within one year of the effective date of the final test rule. No progress reports shall be required.

2. The aquatic vertebrate and invertebrate chronic toxicity tests shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final test rule if those criteria necessary to trigger chronic aquatic toxicity testing are met. No progress reports shall be required.

3. The subchronic toxicity and recovery tests shall be completed and the final results submitted to the Agency within one year of the effective date of the final test rule. Progress reports shall be submitted quarterly.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

M. Issues

1. This proposed rule identifies various OTS test guidelines and other published test methods as test standards for health and environmental effects testing of BPA. The Agency is soliciting comments as to whether the health and environmental effects test guidelines and other cited methods are appropriate and applicable for the testing of BPA. Also regarding the testing of BPA, the Agency requests comments on the adequacy of this testing, the reporting times for the identified health and environmental effects tests, and the criteria used in the environmental effects testing to trigger the chronic aquatic toxicity studies.

2. The Agency is soliciting comments on which of the procedures specified in the OTS Environmental Effect Test Guidelines and the OTS Health Effect Test Guideline for Subchronic Inhalation Testing should be made mandatory.

3. Comments are requested on whether the Agency should define BPA-respirable particles for use in the subchronic inhalation toxicity testing guideline as particles having an aerodynamic diameter enabling them to be inhaled deep into the lungs where gaseous exchange occurs (respiratory bronchioles and alveoli). For man, the Agency believes this is a BPA particle size ranging from 0.1 to 5μm.

4. EPA is requesting comments on whether a concurrent control group should be required in the subchronic inhalation toxicity study; whether a vehicle should be used; and if the toxic properties of the vehicle are not known or cannot be made available, whether both untreated and vehicle control group should be tested.

5. Comments are requested on EPA's belief that a satellite group of 20 animals (10 animals per sex) for the inhalation study be included with the high concentration level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects with a post-treatment period of not less than 21–35 days.

6. EPA is soliciting comments on whether the clinical examination to be conducted in the inhalation study be limited to an acid/base balance determination of the blood at least three times; just prior to initiation of dosing (base line data), after approximately 30 days on test, and just prior to terminal sacrifice at the end of the test period.

7. Comments are requested on limiting the gross pathology to an examination of the external surfaces of the body, all orifices, thoracic and abdominal cavities and their contents, and the esophagus, stomach, and upper small intestine.

8. The Agency is also soliciting comments on whether the full histopathological examination should be initially limited only to the respiratory tract and lungs of all animals in the control and high dose groups, and if further examinations of other dose groups should be contingent on the findings of the initial examination.

III. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . ." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory audits/inspections will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for BPA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted

their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Section 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

IV. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical or chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with the consideration of the costs of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for the chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for BPA are estimated to range from $66,900 to $197,000. This estimate includes the costs for both the required minimum series of tests as well as the conditional ones. The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $17,300 to $51,000. Based on the projected 1984 production of 785 million pounds, the unit tests costs range from 0.002 to 0.008 cents per pound. In relation to the current list price of 67 to 71 cents per pound for BPA, these costs are equivalent to 0.003 to 0.01 percent of price.

The Level I economic analysis (Ref. 7) indicates that the potential for adverse economic effects due to the estimated test cost is low. This conclusion is based on the following observations: (1) demand for BPA appears relatively inelastic due to its dominant use as a captive intermediate; (2) the market expectations for BPA are optimistic; and (3) the estimated unit test costs are very low. A Level II analysis is not necessary.

V. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the NTIS (PB 82-140773). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

VI. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, D.C. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9065); In Washington, D.C.: (554-1404); Outside the U.S.A. (operator 202-554-1404), by July 1, 1985. The meeting will not be held if members of the public do not indicate that they wish to make oral presentations. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VII. Judicial Review

When this proposed rule is promulgated, judicial review may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA intends to promulgate this rule for purposes of judicial review two weeks after publishing the final rule in the **Federal Register**. The effective date will be calculated from the promulgation date.

VIII. Public Record

EPA has established a record for this rulemaking, [docket number (OPTS-42067)]. This record includes basic information considered by the Agency in developing this proposal, and appropriate **Federal Register** notices. The Agency will supplement the record with additional information as it is received.

This record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of BPA to the Priority List (49 FR 22389).

(b) Notice of final rule on two-phase test rule development and exemption procedures (49 FR 39774).

(c) Notice of final rulemaking on data reimbursement (48 FR 31786).

(d) Notice of interim final rule on single-phase test rule development and exemption procedures.

(e) TSCA GLP Standards (48 FR 53922).

(f) Rules requiring TSCA section 8(a) and 8(d) reporting on BPA (49 FR 22284 and 22286).

(g) OTS test guidelines and other published test methodologies cited as test standards for this rule.

(2) Support documents consisting of:

(a) Study of availability of test facilities and personnel.

(b) BPA economic analysis.

(3) Communications before proposal consisting of:

(a) Written public and intra- or interagency memoranda and comments.

(b) Records of telephone conversations.

(c) Records or minutes of informal meetings.

(4) Reports—published and unpublished factual materials.

B. References

(1) Aldrich Chemical Company. 1982–1983 Catalog/Handbook of Fine Chemicals. Milwaukee, WI. Aldrich. 1982.

(2) American Industrial Hygiene Association. Bisphenol A (4,4'-isopropylidenediphenol; 2,2-bis[4-hydroxyphenyl]propane). Am. Ind. Hyg. Assoc. J. May–June: 301–304. 1967.

(3) Korenman, Y.I., Gorokhov, A.A. Certain characteristics of extraction of di(hydroxyphenyl) propane. Russ. J. Phys. Chem. 47:2058–2059. (English Translation.) 1973.

(4) The Society of the Plastics Industry, Inc. Bisphenol A—Information. Letter from Fran W. Lichtenberg, SPI, to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA, and appendices A–I. August 2, 1984.

(5) Handbook of Chemical Property Estimation Methods. Octanol/water partition coefficients. Lyman, W.J., Reehl, W.F., Rosenblatt, D.H., eds. New York: McGraw-Hill, pp 1–1 thru 1–14. 1982.

(6) Lowenheim, F.A., Moran, M.K. Faith, Keyes, and Clark's Industrial Chemicals. 4th ed. New York: Wiley, pp. 149–152. 1975.

(7) USEPA. U.S. Environmental Protection Agency. Economic Impact Analysis of Proposed Test Rule for Bisphenol A. Washington, D.C., Office of Toxic Substances, EPA. 1984.

(8) NIOSH. National Institute for Occupational Safety and Health. Computer printout: National Occupational Hazard Survey. Cincinnati, OH. Retrieved May 17, 1984.

(9) NIOSH. National Institute for Occupational Safety and Health. Computer printout: National Occupational Exposure Survey. Cincinnati, OH. Retrieved May 5, 1984.

(10) The Society of the Plastics Industry, Inc. Responses to Toxicology and Exposure Assessment Questions. Letter from Fran W Lichtenberg, SPI, to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA. August 15, 1984.

(11) The Society of the Plastic Industry, Inc. Additional Information. Letter from Fran W Lichtenberg, SPI, to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA. September 5, 1984.

(12) USEPA. U.S. Environmental Protection Agency. Frequency of organic compounds identified in water. Shackelford, W.M., Keith, L.H. Athens, GA., Office of Research and Development, USEPA. PB–600/4–76–062. 1976.

(13) Matsumoto, G., Hanya, T. Organic Constituents in the atmospheric fallout in the Tokyo area. Atmos. Environ. 14–1409–1419. 1980.

(14) Matsumoto, G., Ishiwatari, R, Hanya, T. Gas chromatographic-mass spectrometric identification of phenols and aromatic acids in rain waters. Water Res. 11:693–698. 1977.

(15) The Society of the Plastic Industry, Inc. Additional Information. Letter from Fran W. Lichtenberg, SPI, to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA. August 30, 1984.

(16) Veith, G.H., Macek, K.J., Petrocelli, S.R., Carroll, J. An evaluation of using partition coefficients and water solubility to estimate bioconcentration factors for organic chemicals in fish. Aquatic Toxicology. ASTM STP 707. J.G. Eaton, P.R. Parrish, and A.C. Hendricks, eds., American Society for Testing and Materials, pp. 116–129. 1980.

(17) USEPA. U.S. Environmental Protection Agency. Water Related Environmental Fate of 129 Priority Pollutants. Washington, D.C., Office of Water Planning and Standards, EPA. EPA Publication No. 440/4–79–0296. 1979.

(18) Matsui, S., Murakami, T., Sasaki, T., *et al.* Activated sludge degradability of organic substances in the wastewater of the Kashima Petroleum and Petrochemical Industrial Complex in Japan. Prog. Water Technol. 7(3/4): 645–659. 1975.

(19) Pivovarova, N.E. Biological purification of wastewaters from the production of diphenylolpropane. Teor. Prakt. Biol. Samochishcheniya Zagryaz Vod Tr Vses Soveshich Vop Sanit Gidrobiol. 119–121. (abstract in Russian: English Translation.) 1972.

(20) Dow Chemical U.S.A. Analysis of bisphenol A (p,p') in lagoon feed and 303 outfall (biodegradability data). Memorandum containing report from Dow Environmental Services to L.M. Thomka, Dow. August 6, 1984.

(21) Shell Oil Company. Health and Safety Studies on Bisphenol A. Letter from G.T. Youngblood, Shell, to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA. August 23, 1984.

(22) Polozova, N.L., Radzevenchuk, I.F., Lovkova, T.N. Effectiveness of some disinfectants for controlling out septoria infection in the Leningrad Region. Zap. Lenigr. S–kh. Inst. 270:97–102. (In Russian: English Translation.) 1975.

(23) USEPA. U.S. Environmental Protection Agency. Preliminary Information Review—Bisphenol A (PIR–375). Washington, D.C., Office of Pesticides and Toxic Substances, EPA. EPA Contract No. 68–01–5789. July 31, 1982.

(24) Dow Chemical U.S.A. The acute toxicity of parabis A and bisphenol A to the sheepshead minnow. R&D Report No. D–001226. Dow Chemical U.S.A., Midland, MI. January 1978.

(25) Dow Chemical U.S.A. Bisphenol A biochemical oxygen demand and fish toxicity data. Memorandum from H.C. Alexander, Dow, to L.M. Thomka, Dow. August 21, 1984.

(26) Shell Toxicology Laboratory. The acute toxicity of diphenylolpropane to rainbow trout (*Salmo gairdneri*). GRR–TLGR. 79.146. (Also appendix G to reference 4.) Shell Toxicology Laboratory (Tunstall), Kent, England. November 1979.

(27) Shell Toxicology Laboratory. Diphenylolpropane: acute toxicity to *Daphnia magna* and *Selenastrum capricornutum*. SBGR. 83.216. (Also appendix F to reference 4.) Shell Toxicology Laboratory (Tunstall), Kent, England. May 1983.

(28) USEPA. U.S. Environmental Protection Agency. Bisphenol A—Chemical Hazard Information Profile (draft report). Washington, D.C., Office of Toxic Substances, EPA. September 18, 1981.

(29) Knaak, J.B., Sullivan, L.J. Metabolism of bisphenol A in the rat. Toxicol. Appl. Pharmacol. 8:175–184. 1966

(30) National Toxicology Program. Carcinogenesis bioassay of bisphenol A in F–344 rats and B6C3F1 mice (feed study). Springfield, VA.: National Technical Information Service. PB82–184060. March 1982.

(31) Stasenkova, K.P., Shumskaya, N.I., Grinberg, A.E. Certain laws governing the biological action of bisphenol A derivatives, depending on their chemical structure. Gig. Tr. Prof. Zabol. 6:30–33. (In Russian: English Translation.) 1973.

(32) Bond, G.P., McGinnis, P.M., Cheever, K.L. *et al.* Reproductive effects of bisphenol A. Paper No. 69 presented at the Society of Toxicology's 19th Annual Meeting, Washington, D.C. March 9–13, 1980 (abstract).

(33) Hardin, B.D. Bond, G.P., Sikov, M.R., Andrew, F.D., Beliles, R.P., Niemeier, R.W. Testing of selected workplace chemicals for teratogenic potential. Scand. J. Work. Environ. Health. 7 (suppl. 4):66–75. 1981.

(34) General Electric Company. Bisphenol A—TSCA section 8(d) submission. Letter from Ladd W. Smith, G.E., to Philip Wirdzek, Office of Pesticides and Toxic Substances, EPA. August 23, 1984.

(35) Goodman, L.R., Middaugh, D.P., Housen, D.J., *et al.* Early life-stage toxicity test with tidewater silversides (*Menidia peninsulae*) and chlorine-produced oxidants. Environ. Toxicol. and Chem. 2:337–342. 1983

(36) Szap, P., Kesse, L., Klapp, J. The analysis of bisphenol A by high performance liquid chromotography. J. Liq. Chromotogr. 1(1):89–96. 1978.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E–107, 401 M St., SW., Washington, D.C. from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

IX. Other Regulatory Requirements

A. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This test rule is not major

because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the actual cost of all the proposed testing for BPA is estimated to range from $66,900 to $197,000 or less than $1 million over the testing and reimbursement period. Second, the cost of the testing is not likely to result in a major increase in users' costs or prices. Finally, based on our present analysis, EPA does not believe that there will be a significant adverse effect as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.* Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They will not perform testing themselves, or will not participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB number 2070-0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Environmental protection, Hazardous material, Chemicals, Testing, Reporting and recordkeeping requirements.

Dated: May 7, 1985.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

It is proposed that 40 CFR Part 799 be amended as follows:

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Part 799 is amended by adding § 799.940 to subpart B to read as follows:

§ 799.940 Bisphenol A.

(a) *Identification of test substance.* (1) Bisphenol A (CAS No. 80-05-7) (hereinafter "BPA") shall be tested in accordance with this rule.

(2) BPA of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture or process BPA from the effective date of this rule (44 days from the publication date of the final rule in the Federal Register) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests and submit data as specified in this section. Subpart A of this Part, and Part 790—Test Rule Development and Exemption Procedures for Single-phase Rulemaking.

(c) *Environmental effects testing*—(1) Aquatic acute toxicity—(i) *Required testing.* (A) Aquatic vertebrate, invertebrate, and aquatic plant acute toxicity tests shall be conducted with BPA with the fathead minnow (*Pimephales promelas*), silversides (*Menidia peninsulae*), *Daphnia magna*, *Mysidopsis bahia*, *Selenastrum capricornutum*, and *Skeletonema costatum* in accordance with the OTS Environmental Effects Test Guidelines for acute aquatic toxicity testing (EG-1, 3, 8, and 9), published by the NTIS (PB 82-232992), and other cited methods which are incorporated by reference.

(B) The OTS Environmental Effects Test Guidelines for acute toxicity testing were published by the EPA with the publication number EPA-560/6-82-002 and are for sale from the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia, 22161. When ordering use NTIS Accession No. PB 82-232992. These guidelines are also available for inspection at the Office of the Federal Register, Room 8301, 1100 L Street NW., Washington, D.C. 20005. A copy of this publication has also been included in the public record for this rule (docket no. OPTS-42067) and is available for inspection in the OPTS Reading Room, E-107, 401 M Street, SW., Washington, D.C. 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. This incorporation by reference was approved by the Director of the Federal Register on [date]. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the Federal Register.

(C) The document "Bioassay Procedures for the Ocean Disposal Permit Program," which specifies acute toxicity testing procedures for *Menidia peninsulae*, has the EPA document Publication No. EPA-600/9-78-010 and is dated March 1978. A copy of this procedure is included in the public record for this rule (docket no. OPTS-42067) and is also available for inspection at the Office of the Federal Register, Room 8301, 1100 L Street NW., Washington, D.C. 20005. This incorporation by reference was approved by the Director of the Federal Register on [date]. This document is also available from EPA, Office of Research and Development, Technical Information Staff, Cincinnati, OH 45268. This material is incorporated as it exists on the date of the approval and a notice of any changes in it will be published in the Federal Register.

(ii) *Reporting requirements.* (A) The acute toxicity tests shall be completed and the final results submitted to the Agency within one year of the effective date of the final rule.

(B) No quarterly progress reports are required to be submitted.

(2) *Aquatic chronic toxicity*—(i) *Required testing.* (A) Aquatic vertebrate and invertebrate chronic toxicity tests shall be conducted with BPA using the most sensitive vertebrate and invertebrate test species (i.e., that with the lowest LC_{50} value or in the absence of an LC_{50} less than 1 ppm the test species that showed the greater tendency for chronicity) from the acute toxicity testing conducted in accordance with paragraph (c)(1)(i) of this section if the following criteria are met. The chronic test shall be conducted only if the 96-hour LC_{50} value for the test species is less than 1 ppm, or there are indications of chronicity (i.e., the ratio of the 48 hour to 96 hour LC_{50} greater than 2) in that species. If neither of these criteria is met, chronic testing is not required. The chronic testing, if required, shall be conducted in accordance with the OTS Environmental Effects Test Guidelines for chronic toxicity (EG-4 and 11), published by the NTIS (PB 82-232992), and other cited methods which are incorporated by reference.

(B) The OTS Environmental Effects Test Guidelines for chronic toxicity testing are incorporated by reference and available as described above in § 799.940(c)(1)(i)(B).

(C) The chronic aquatic toxicity testing procedures to be used for BPA testing in *Menidia peninsulae* are specified in a publication by Goodman

et al. entitled "Early life-stage toxicity test with tidewater silversides (*Menidia peninsulae*) and chlorine-produced oxidants" available in *Environmental Toxicology and Chemistry*, Vol. 2, pp. 337–342, 1983. A copy of this publication has been included in the public record for this rule (docket no. OPTS–42067) and is available for inspection in the OPTS Reading Rm., E–107, 401 M St., SW., Washington, D.C. 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. This incorporation by reference was approved by the Director of the Federal Register on [date]. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **Federal Register.**

(ii) *Reporting requirements.* (A) Chronic toxicity tests shall be completed and the final results submitted to the Agency within two years of the effective date of the final rule.

(B) No quarterly progress reports are required to be submitted.

(e) *Health effects testing*—(1) *Subchronic toxicity*—(i) *Required testing.* (A) Subchronic toxicity and recovery tests shall be conducted with BPA in accordance with the OTS Health Effects Test Guidelines for Subchronic Exposure/Inhalation Toxicity, published by the NTIS (PB 83–257691) which is incorporated by reference.

(B) The OTS Health Effects Test Guideline for Subchronic Toxicity/Inhalation Toxicity was published by the EPA with the publication number EPA 560/6–83–001 and is for sale from the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia, 22161. When ordering use NTIS Accession No. PB 83–257691. It is also available for inspection at the Office of the Federal Register, Rm. 8301, 1100 L Street NW., Washington, D.C. 20005. A copy of this publication has also been included in the public record for this rule (docket no. OPTS–42067) and is available for inspection in the OPTS Reading Rm., E–107, 401 M St., SW., Washington, D.C. 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. This incorporation by reference was approved by the Director of the Federal Register on [date]. These materials are incorporated as they exist on the date of the approval and a notice of any change in these materials will be published in the **Federal Register.**

(ii) *Reporting Requirements.* (A) Subchronic toxicity tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(B) Progress reports shall be submitted quarterly.

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033.)

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